

DOCKET NO. JAB-1425

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Bart De Corte, et al.

Serial No.: 09/430,966

Art Unit: 1624

Filed : November 1, 1999

Examiner: V. Balasubramanian

For : HIV REPLICATION INHIBITING PYRIMIDINES

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February 13, 2004

(Date of Deposit)

Jesús Juanós i Timoneda

(Name of applicant, assignee, or Registered Representative)

(Signature)

February 13, 2004

(Date of Signature)

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed find:

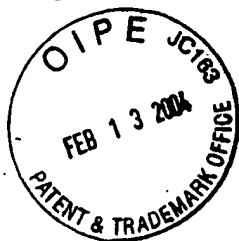
- Supplemental Declaration (<sup>12</sup>~~50~~ pages)
- IDS - Form 1449 and references

In the event of any non-payment of a required fee, the Commissioner is authorized to charge or credit Deposit Account No. 10-0750/JAB1425/JJiT in the name of Johnson & Johnson as required to correct the error.

Respectfully submitted,

Jesús Juanós i Timoneda  
Reg. No. 43,332  
Attorney for Applicant(s)

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-1513  
DATE: February 13, 2004



Docket No. JAB 1425

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Bart DE CORTE et al.

Serial No. : 09/430,966 Art Unit: 1624

Filed : 11/01/1999 Examiner: VENKATARAMAN BALASUBRAMANIAN

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PO Box 1450  
Alexandria, VA 22313-1450

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This copy is supplemental to the First Supplemental  
Information Disclosure Statement mailed on August 11, 2003.

Pursuant to 37 C.F.R. §1.56 and in accordance with 37  
C.F.R. §§1.97-1.98, information relating to the above-identified  
application is hereby disclosed. Inclusion of information in  
this statement is not to be construed as an admission that this  
information is material as that term is defined in 37 C.F.R.  
§1.56(b).

Applicant(s) reserve(s) the right to establish the  
patentability of the claimed invention over any of the  
information provided herewith, and/or to prove that this  
information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required. *THIS IDS FILING PROVIDES COPIES OF REFERENCES AND COPIES OF FULL ARTICLES THAT WERE LISTED ON PTO-1449 FILED WITH AN RCE ON JAN. 23, 2004, AND RESUBMITTED BY HAND DELIVERY ON FEB 4, 2004.*

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached);  
or  
☐ Please charge Deposit Account No. 10-  
0750/ / the fee of \$180.00 as set forth in  
§1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with \$1.97(e) (attached);  
or  
☐ Please charge Deposit Account No. 10-  
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☐ In accordance with \$1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under \$1.113 or a Notice of Allowance under \$1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with \$1.97(e) as set forth below and the fee of \$180.00 as set forth in \$1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith.

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ ~~There are no listed references which are not in the English language.~~ AN ENGLISH TRANSLATION OF ONE REFERENCE THAT IS NOT IN THE ENGLISH LANGUAGE WILL BE PROVIDED TO THE EXAMINER AS SOON AS AVAILABLE.

☐ The relevance of those listed references which are not in the English language is as follows:

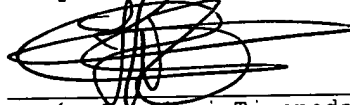
☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

Copies of the references listed on the search report(s) are included except for those previously cited in an IDS mailed .

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/JAB 1425/JJiT. This form is submitted in triplicate.

Respectfully submitted,



Jesús Juanos i Timoneda  
Reg. No. 43,332  
Attorney for Applicants

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-1513  
DATED: February 13, 2004



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

Application Number	09/430,966
Filing Date	11/01/1999
First Named Inventor	Bart De Corte
Group Art Unit	1614
Examiner Name	V. Balasubramanian
Attorney Docket Number	JAB 1425

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Misc.
		Number	Kind Code <sup>2</sup> (if known)			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Translation	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
	1	EP	0 588 762	A1	CIBA-GEIGY A.G.	08-23-1993	To be submitted	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. <sup>6</sup> If possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 3

Application Number	09/430,966
Filing Date	11/01/1999
First Named Inventor	Bart De Corte
Group Art Unit	1614
Examiner Name	V. Balasubramanian
Attorney Docket Number	JAB 1425

OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	Translation	T <sup>2</sup>
	2	GRUZDEV, et al., <i>A Randomized, double-blind, placebo-controlled trial of TMC125 as 7-day monotherapy in antiretroviral naïve HIV-1 infected subjects</i> , AIDS 2003, VOL 17, pp. 2487-2494.	No	
	3	SANKATSING, et al., <i>TMC125 exerts similar initial antiviral potency as a five-drug, triple class antiretroviral regimen</i> , AIDS 2003, Vol. 17, pp. 2623-2627.		
	4	GAZZARD, et al., <i>An open-label assessment of TMC 125 - a new, next-generation NNRTI, for 7 days in HIV-1 infected individuals with NNRTI resistance</i> , AIDS 2003, Vol. 17, pp. 49-54.		
	5	LUDOVICI, et al., <i>Evolution of Anti-HIV Drug Candidates. Part 3: Diarylpyrimidine (DAPY) Analogues</i> , Bioorganic & Medical Chemistry Letters 11, 2001, pp. 2235-2239.		
	6	UDIER-BLAGOVIĆ, et al., <i>Validation of a Model for the Complex of HIV-1 Reverse Transcriptase with Nonnucleoside Inhibitor TMC125</i> , J. AM. CHEM. SOC. 2003, Vol. 125, pp. 6016-6017.		
	7	GULICK, <i>New Antiretroviral Drugs</i> , Clinical Microbiology and Infectious Diseases, CMI, 9, (3) pp. 186-193 (March, 2003)		
	8	FURUKAWA, et al., <i>Syntheses of Compounds related to Guanidine and their Inhibitory Action on Growth of HeLa Cells</i> , Chem. Pharm. Bull. 9 (11), 914-921 (1951)		
	9	GAZZARD, et al., <i>TMC125, A Next-Generation NNRTI, Demonstrates High Potency After 7 Days Therapy in Treatment-Experienced HIV-1 Infected Individuals with Phenotypic NNRTI</i> , CROI, Seattle, Feb. 2002.		
	10	VINGERHOETS, et al., <i>Antiviral activity of TMC125, a potent next-generation NNRTI, against &gt; 5000 recombinant clinical isolates exhibiting a wide range of (NNRTI) resistance</i> , XIIth International HIV Drug Resistance Workshop, June 10-14, 2003, Mexico.		
	11	VINGERHOETS, et al., <i>Characterization of Resistance Before and After Short-Term Therapy with TMC125 in Patients with Documented NNRTI Resistance</i> , XIIth International HIV Drug Resistance Workshop, June 10-14, 2003, Mexico		
	12	GAZZARD, et al., <i>TMC125, a Next Generation NNRTI, Demonstrates High Potency After 7 Days Therapy in Treatment-Experienced HIV-1 Infected Individuals with Phenotypic NNRTI-Resistance</i> , XIV International AIDS Conference, July 2002, Barcelona, Spain		
	13	SANKATSING, et al., <i>TMC 125 Monotherapy for One Week Results in a Similar Initial Rate of Decline of HIV-1 RNA as Therapy With a 5-Drug Regimen</i> , CROI, Seattle, Feb., 2002.		
	14	ARNOLD, et al., <i>Inhibitor conformational flexibility and positional variation are important for activity against drug-resistant virus: crystal structures of highly potent non-nucleoside inhibitors of HIV-1 reverse transcriptase</i> , 21 <sup>st</sup> European Crystallographic Meeting, Durban, South Africa, 24-29, Aug. 2003.		

Examiner Signature	Date Considered
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